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EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/854,523

Applicant(s)

BERGER ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 14-18, 20-23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 14-18, 20-23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 14-21, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 28 is rendered indefinite since it is unclear whether the limitation "said central unit being provided with an analyzer for measuring at least one parameter or parameter group of said medical sample to be analyzed" means that the central unit has its own internal analyzer or the central unit is to be coupled with an analyzer. If it is the former, there is a new matter situation. If it is the latter, then the language is considered to be indefinite since the claim later recites "at least one portable independent single analyzer...", such that it is unclear if the analyzer of the central unit is the same as that of the at least one portable independent single analyzer.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 2-12, 14, 15, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,519,635 to Miyake et al.

Miyake et al. disclose an analyzing system for analyzing samples (abstract; figs. 1-17; col. 2, lines 26-41). The properties, concentration, and others of dissolved constituents in fluid are measured (col. 1, lines 8-11). Although Miyake et al. do not explicitly disclose the analyzing system is for analyzing medical samples particularly measuring blood gases, pH, electrolytes, metabolites, Co-oximetry, hematology, coagulation, and immunology, the limitation is considered by the Examiner a recitation of intended use of the claimed invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPQ 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

A computer-supported central unit (2) has an input/output unit as characterized by the busy transfer of liquids, energy, and data from and to the analyzer and detector, which measures samples and transmits information back to the central unit for display on display portion (8) (col. 5, lines 48-56). The central unit has a vessel for carrier liquid (91), vessel for reagents (92), and vessel for waste liquid (93) (col. 9, lines 1-15). A plurality of portable independent single analyzers (11,12,13,14) is selected and may be simultaneously attached to the central unit, such that the analyzers are capable of being in three positions including prior to inserting the analyzers into the central unit, connecting the analyzers to the central unit, and disconnecting the analyzers

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from the central unit (col. 10, lines 40-49; col. 11, lines 23-34). Each of the single analyzers is provided for determining one sample parameter or sample parameter group in conjunction with central unit (col. 6, lines 1-17 and 48-67).

Although Miyake et al. do not explicitly disclose a “*charging position*”, “*measuring position*”, and “*bedside measuring position*”, the limitations are considered by the Examiner a recitation of intended use of the claimed invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPQ 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the instant specification has not provided a working definition of “charging position”, “measuring position”, and “bedside measuring position”. Additionally, it is unclear whether “charging position”, “measuring position”, and “bedside measuring position” are part of the claims. For examining purposes, if the analyzer is capable of being in two different positions--a first position and a second position, it meets the claim. The abbreviation “i.e.” is defined by <http://www.dictionary.com> as that is; that is to say; or in other words as if examples or options are to follow. The phrases “i.e. charging position” and “i.e. measuring position” do not further limit the claim since it is interpreted as giving an example of what the first position and second positions could be. It is suggested that i.e. be omitted from the claims to clarify the claims. Note: The language “portable single analyzers are *designed* so as to be

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removable from said charging position and to be transferred in a second position, i.e., a measuring position" require only the capability of being removed.

The central unit is provided with a memory portion for storing sample processing steps and observed data corresponding to plural analytical items, controller for reading out signals from the memory portion and controlling the liquid controlling means and detecting means, and signal processor for reading out processing methods of observed data stored in the memory portion and processing observed data (claim 8). The central unit includes docking stations with liquid and signal connector (4) for releasable plug-in and docking connections for at least one of data, energy, fluid, and sample transport (figs. 1-17; col. 8, lines 26-31). Since Merriam-Webster Collegiate Dictionary defines a socket as an opening or hollow that forms a holder for something. The liquid and signal connector (4) of the central unit and liquid signal connectors of the analyzers (41,42,43,44) have openings or sockets in which tubes project from these openings or sockets for the transfer of data, energy, fluid, and sample (fig. 13). The docking stations and sites of the analyzers appear identical in construction (figs. 11, 12, and 15). Each of the analyzers has a connector for liquids and connector for electrical signals (41,42,43,44) both of which are connected to the liquid and signal connector of the central unit (figs. 1-17; col. 8, lines 32-35; col. 10, line 18-col. 13, line 52). The liquid connector has three connectors, such as a connector for reagent supply, connector for sample liquid, and connector for transferring mixed and reacted sample to the central unit (figs. 1-17; col. 8, lines 32-40; col. 10, line 18-col. 13, line 52). Signal wires from two memories (112,113) are connected to the liquid-signal connector (41,42,43,44) in the analyzer (col. 8, lines 51-53; col. 10, line 18-col. 13, line 52). Memory (113) stores information on adequate samples for analytical methods, amounts, flow rate and

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mixing timing of reagents (col. 8, lines 53-56). Memory (112) stores setting methods for measuring conditions and processing methods of data (col. 8, lines 56-58).

When the liquid-signal connectors (41,42,43,44) of the analyzers are connected to the liquid and signal connector (4) of the central unit, the pump-valve controller (61) and signal processor (62) in the central unit start to operate and take in signals describing processing steps, analytical methods, and data processing method of samples for each analysis from memories (112,113,122,123,132,133,142,143) of the analyzers through liquid-signal connectors (41,42,43,44) (col. 11, lines 27-34). Pump (531) supplies sample to the analyzers through flow systems (561,562,563,564) via liquid and signal connector (4) and liquid-signal connectors (41,42,43,44) (col. 10, line 18-col. 13, line 52). Pump (542) supplies reagents to the analyzers through flow systems (571,572,573,574) via liquid and signal connector (4) and liquid-signal connectors (41,42,43,44) (col. 10, line 18-col. 13, line 52). While mixing and reaction are performed in the analyzers by operating the pumps (531,541), carrier liquid and operating liquid for supplying reagents are also supplied to the analyzers concurrently for cleaning the flow paths of the analyzers (col. 11, lines 59-65). Flow paths (741,742,743,744) extend from each of the analyzers to a reacted sample distributing valve (58) after which a flow cell for detecting (71) is connected (col. 11, lines 10-19). It appears that an energy supply bus is provided within the bus system since energy is required to operate the bus system.

6. Claims 2, 14, 15, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0252 631 to Lillig et al.

Lillig et al. disclose an analyzing system (127) for analyzing medical samples (see FIGS. 1-5; ABSTRACT). Since patient samples are being analyzed, body fluids are analyzed. The

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system is suitable for use in hospitals and commercial laboratories (see COL. 1, lines 4-7). The system (127) comprises of analysis modules (24-30,34) within modular analyzer (10) and analysis means (80-84) within modular analyzer (60) (see FIGS. 1-5; COL. 3, lines 30-56; COL. 4, lines 1-43; COL. 5, lines 5-50; CLAIM 1). Analysis modules (24-30,34) may be similar to various modules included in the ASTRA Analyzer from Beckman Instruments, Inc. of Brea, California (see COL. 3, lines 45-56; COL. 4, line 1). Analysis module (34) is capable of analyzing electrolytes, including chloride, sodium, potassium, and carbon dioxide (see COL. 3, lines 49-56; COL. 4, line 1). The work surface of modular analyzer (10) is supported by a frame (42), which supports an electronics card cage (44), which includes a plurality of circuit boards (46), disk drive (47), and related electronic circuitry for controlling the modular analyzer (10) (see COL. 4, lines 10-15). A computer terminal, including a keyboard and printer, are connected to the electronic circuitry of the card cage (44) for providing instructions to and receiving results from the modular analyzer (10) (see COL. 4, lines 17-23). The modular analyzer (60) includes a card cage (114), which holds a disk drive (115) and plurality of circuit boards containing the control and analysis electronics of modular analyzer (60) (see COL. 6, lines 47-50). A computer terminal, including a keyboard and printer, are connected to the control and analysis electronics for providing test and operating instructions to the modular analyzer (60) (see COL. 6, lines 50-55). The modular analyzers (10,60) may be operated independently to perform clinical chemistry tests, addressing certain distinct capacity, menu and throughput capabilities needed in clinical chemistry laboratories in one position (see COL. 7, lines 44-48). The modular analyzers (10,60) may be joined to form a single clinical chemistry system (127), possessing the attributes of both analyzers (10,60) while significantly decreasing operator workload and involvement as



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compared to two separate analyzers in another position (see FIG. 3; COL. 7, lines 48-58; COL. 8, lines 1-17). The modular analyzers (10,60) are joined by placing spacers (136) between holes (50) and (118), retaining them by bolts (138) and nuts (140), and inserting locating pins (142) into the holes (56,58,124,126) within the corresponding index plates (52,54,120,122) (see COL. 8, lines 2-8). A false panel (143) is installed between the modular analyzers (10,60) to maintain separate cooling airflow within the respective modular analyzers (10,60) (see COL. 8, lines 8-11). When the modular analyzers (10,60) are joined, electronic, electrical, and fluid interfaces are also provided between the analyzers (10,60) to form the system (127) (see FIGS. 3-5; COL. 8, lines 33-35). It appears that the docking stations and sites are of uniform type, such that electronic, electrical, and fluid interfaces can be formed between the analyzers. Interface circuit cards (144) and (146) are installed into the card cages (44) and (114) and suitable cabling (147) is connected therebetween (see COL. 8, lines 35-38). It appears that sockets receiving the cabling between the modular analyzers (10,60) would be inherent, as there is a need for the cabling to be received in something. Interface card (146) provides program, data, and timing signals vial cabling (147) to the card (144) (see COL. 8, lines 41-43). Operating software for one or more microprocessors in the modular analyzer (10) may be loaded from the disk drive (115) through the interface cards (146) and (144) to suitable memory means within the modular analyzer (10) (see COL. 8, line 56; COL. 9, lines 1-4). The cards (144) and (146) allow the results of tests performed by the modular analyzer (10) to be relayed to the modular analyzer (60), such that the results are combined with results produced by the modular analyzer (60) and displayed on the terminal or printed on the printer connected to the modular analyzer (60) (see COL. 9, lines 5-12). Because all test identification and operational control for the system (127)

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is made via the terminal and printer connected to the modular analyzer (60), the terminal and printer connected to the modular analyzer (10) may be removed (see COL. 9, lines 12-16). The modular analyzers (10,60) may both include the same microcomputer bus structure that is interconnected by the interface cards (144) and (146), such that software, operating information and instructions, test results, and timing and clear signals maybe transferred between the microcomputer bus in each of the modular analyzers via the interface cards (144,146) (see COL. 9, lines 46-50). It appears that an energy supply bus is provided within the bus system since energy is required to operate the bus system. Since the bus system operates to control the transfer of sample between the analyzers, it appears that there is a sample bus for exchange of sample fluids. Since Applicant has not provided a working definition of a bus, Examiner has used Merriam-Webster's definition, which defines bus as a set of parallel conductors in a computer system that forms a main transmission path, in light of the prior art, which appears to describe "bus" as signal transmission lines. A sample, data, fluid, or energy bus is a signal transmission lines within an electronic structure dictating instructions on handling sample, data, fluid, or energy, respectively. The control and analysis electronics in the modular analyzer (60) may also directly access the microcomputer bus within the modular analyzer (10) for the transfer of data or instructions (see COL. 9, lines 54 and 55; COL. 10, lines 1-4). The modular analyzer (60) provides instructions to control and maintain the analyzers. The modular analyzers (10,60) share a common source of wash fluid in the system (127) (see COL. 10, lines 5-7). Concentrated wash solution from a reservoir (148) is supplied to a valve (149) and deionized water from a suitable source is applied to a similar solenoid valve (150) (see COL. 10, lines 7-10). The outputs of the valves are connected at a T connection to a solenoid controlled diverter valve

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(151), which either supplies diluted wash solution to a reservoir or supply tank (152) in the modular analyzer (10) or to reservoirs or supply tanks (154,156) in the modular analyzer (60) (see COL. 10, lines 10-15). A fluid sensor (158) senses the level of wash fluid in the reservoir (152) (see COL. 10, lines 15 and 16). The sensor is connected through false panel (143) via connector (160) to a bus carrying signals from level sensors (160,162,164) on each of the reservoirs (148,154,156) (see COL. 10, lines 17-20). The signals from the sensors (158-164) are applied to the control electronics in the card cage (114), and in response, the control electronics control valves (149-151) to replenish diluted wash solution in the reservoirs (154-158) (see COL. 10, lines 20-25). A wash fluid drain line (168) is connected from the modular analyzer (10) through the false panel (143) into a drain reservoir (170), which holes used wash fluid from the modular analyzer (60) (see COL. 10, lines 26-29).

It is noted that claim 28 is subject to a reasonably broad interpretation of at least one single analyzer in which there could be only one single analyzer for examining purposes. It is noted that the system of Lillig et al. has analyzers within analyzers. The analysis modules (24-30,34) of the modular analyzer (10), the totality of the modular analyzer (10) including the analysis modules (24-30,34), analysis means (80-84) of the modular analyzer (60), or the totality of the modular analyzer (60) including the analysis means (80-84) could be interpreted as the single analyzer(s) coupled to the computer terminal associated with either modular analyzer (10,60). The totality of the modular analyzer (10,60) along with its associated computer terminal; or each of the modular analyzers (10,60) may also be interpreted as the single analyzers coupled to either computer terminal associated with the modular analyzers (10,60). For examining purposes, the modular analyzer (60) has been interpreted as the computer-supported

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central unit with analyzing means (80-84), such that either the analysis modules (24-30,34) or the totality of the analyzer (10) along with the analysis modules (24-30,34) may be the single analyzer(s).

Referring to claim 2, the recitation of using the analyzers in a first and second positions, wherein the second position is a bedside measuring position is method limitation that is accorded no patentable weight in an apparatus claim.

7. Claims 2-4, 6, 8-11, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,331,962 to Neumann.

Neumann discloses an analyzing system for analyzing medical samples (abstract; col. 7, lines 20-23). A computer-supported central unit has an input/output unit (figs. 5 and 12). A plurality of portable independent single analyzers (1,2,3,4) may be simultaneously coupled in a first position to a central unit to form a multi-component analyzer (figs. 5 and 12). The analyzers are designed so as to be removable from the charging position to be transferred in a second position, i.e. a bedside measuring position, such that physiological signals may be obtained (col. 7, lines 20-46). A bus system is provided for establishing releasable contact between each of the analyzers and between the analyzers and central unit in the charging position (fig. 5) via docking stations with releasable plug-in and docking connections with tubes/cables projecting from the sockets (fig. 5). The bus system is provided with a data bus to establish a data link between the analyzers and central unit and energy supply bus (figs. 5 and 14; col. 5, line 12-col. 9, line 56). It appears that the docking stations and sites are identical in construction.

8. Claims 2-4, 6, 8-11, 27 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,524,240 to Thede.

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Thede discloses an analyzing system for analyzing medical samples (abstract; figs. 1-7). A computer-supported central unit has an input/output unit (figs. 1-7; col. 7, lines 24-35). A plurality of portable independent single analyzers (10) may be simultaneously coupled in a first position to a central unit to form a multi-component analyzer (figs. 1-7). The analyzers are designed so as to be removable from the charging position to be transferred in a second position, i.e. a bedside measuring position, such that physiological signals may be obtained (abstract). A bus system is provided for establishing releasable contact between each of the analyzers and between the analyzers and central unit in the charging position via docking stations with releasable plug-in and docking connections with tubes/cables projecting from the sockets (figs. 1-7). The bus system is provided with a data bus to establish a data link between the analyzers and central unit and energy supply bus (abstract). It appears that the docking stations and sites are identical in construction.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 16-18, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,519,635 to Miyake et al. or EP 0252 631 to Lillig et al. or U.S. Patent No. 4,331,962 to Neumann or U.S. Patent No. 6,524,240 to Thede.

Regarding claims 16-18, Miyake et al. and Lillig et al. and Neumann and Thede each do not explicitly disclose the central unit with a connection for remote data transmission, such as intranet or internet connection. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Miyake et al. or Lillig et al. or Neumann or Thede to provide the central unit with a connection for remote data transmission, such as intranet or internet connection, as it is well known to communicate or transmit information or receive information within the organization in a secure manner through intranet or communication or transmit information or receive information with other outside organization or look up pertinent information through the internet.

Regarding claims 25 and 26, Miyake et al. and Neumann and Thede each do not explicitly disclose the analyzer and central unit with transmitter/receiver systems for wireless

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data transfer effected by wireless technology in the 2.4 GHz range using a license-free ISM band. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Miyake et al. or Neumann or Thede to provide the analyzer and central unit with transmitter/receiver systems for wireless data transfer effected by wireless technology in the 2.4 GHz range using a license-free ISM band, which is commercially available and avoids the use disorganized wires, making the analyzer more portable.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,519,635 to Miyake et al. in view of U.S. Patent No. 5,631,844 to Margrey et al.

Miyake et al. do not specify what the analyzers measure. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Miyake et al. to analyze the claimed parameters, such as analyze blood gases for electrolytes as in Margrey et al. as they are very well known and helpful in medical diagnoses as taught by Margrey et al. (col. 5, lines 20-25).

14. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,519,635 to Miyake et al. in view of U.S. Patent No. 6,249,774 to Roden et al. or U.S. Patent No. 4,737,910 to Kimbrow.

Miyake et al. do not explicitly disclose the claimed inventory management system in the central unit. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the central unit of the analyzer of Miyake et al. to provide the claimed inventory management system, as it is very well known, commercially available, and advantageous to prevent depleting of supplies and materials for performing analysis as taught by Roden et al. or Kimbrow.

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15. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,519,635 to Miyake et al. or U.S. Patent No. 4,331,962 to Neumann or U.S. Patent No. 6,524,240 to Thede in view of U.S. Patent No. 5,614,415 to Markin.

Miyake et al. disclose that the analyzers are for multi-purpose use. Miyake et al. and Neumann and Thede each do not explicitly disclose that the central unit is provided with a data link to a laboratory system, laboratory information system, or hospital information system. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the analyzer of Miyake et al. or Neumann or Thede to provide the central unit with a data link to a laboratory system, laboratory information system, or hospital information system for rapid and efficient reporting of tests results and improving laboratory quality and efficiency since there is operation and data overlap between the hospital and laboratory as taught by Markin (see COLS. 1-5).

#### ***Response to Arguments***

16. Applicant's arguments filed 3/1/2004 have been fully considered but they are not persuasive.

17. Applicant argues that assembling and disassembling of analyzers (10) and (60) of LILLIG is very complicated time-consuming work. Applicant states that in contrast to the LILLIG system, the analyzing system of the present invention comprising portable take away single analyzers coupled to a central unit in a charging position. Applicant states that the instant analyzers can be easily removed from the charging position for use in a bedside measuring position. Applicant states that the instant analyzers will permit the system to be used as an automatic multi-component analyzer with flexible extension capacity, whose components can



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easily be exchanged for different ones. Applicant states that it will be possible to remove the analyzers from the charging position without any effect and transfer them to a measuring position, preferably next to the patient for sample analysis in a decentralized manner. Applicant states that the analyzing system will allow the use of diverse single analyzers for measuring different parameters or parameter groups and of a plurality of identical single analyzers for measuring one and the same parameter group if an increase in sample throughput is desired. Applicant argues that the LILLIG system cannot be used in such a flexible manner. Examiner notes that Applicant admits that the analyzers can be taken apart, such that they are movable to a different position. In col. 7, line 44-col. 8, line 17 of Lillig, it states that the analyzers may be used joined or separated by removing spacers, bolts, nuts, and pins. The fact that the analyzers of Lillig can be separated is a demonstration of each analyzer's ability to be removable and portable, which is defined by Merriam-Webster Collegiate Dictionary as capable of being carried or moved about. It does not matter how easy it is to separate the analyzers. They are removable, separable, and individually or in combination portable. The claim requires only the capability of the analyzers to be brought in a first position and a second position. Additionally, whether the analyzers are connected or separated from each other, they are portable since they movable individually or movable as a connected unit.

### ***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 2-12, 14-18, 20-23, and 25-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-40 of copending Application No. 09/854560. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '560 are combination claims including all the limitations of claims <sup>2-12, 14-18, 20-23 and 25-28</sup> ~~1-26~~ of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Original independent claim 1 has been cancelled, and new independent claims 27 and 28 have been added. Claim 27 recites "a plurality of portable independent single analyzers...wherein said portable single analyzers are simultaneously coupled in a first position..." Claim 28 recites "said central unit being provided with an analyzer for measuring at least one parameter or parameter group of said medical sample to be analyzed" and "at least one portable independent single analyzer..." Furthermore, Lillig has been maintained for claim 28 and its dependent claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner  
Art Unit 1743

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